Comparison of the Current WHO and New ADA Criteria for the Diagnosis of Diabetes Mellitus in Three Ethnic Groups in the UK

N. Unwin*[1,2,3], K.G.M.M. Alberti[1,2], R. Bhopal[3], J. Harland[1,2], W. Watson[1,2], M. White[3]

[1]*Human Metabolism and Diabetes Research Centre, University of Newcastle, Newcastle upon Tyne, UK*
[2]*Department of Medicine, University of Newcastle, Newcastle upon Tyne, UK*
[3]*Department of Epidemiology and Public Health, University of Newcastle, Newcastle upon Tyne, UK*

The American Diabetes Association have recommended that the fasting plasma glucose level for the diagnosis of diabetes is lowered and that this becomes the main diagnostic test. We have used population-based data from three ethnic groups in Newcastle upon Tyne to examine the implications of this change. Data were available on 824 European (25–74 years), 375 Chinese (25–64 years), and 680 South Asian (25–74 years) subjects. All subjects apart from those reporting a prior diagnosis of diabetes underwent a standard 75 g oral glucose tolerance test (WHO criteria) which included the measurement of fasting glucose. The prevalence of diabetes was higher in all three ethnic groups using the new ADA criteria compared to the WHO criteria: 7.1 % vs 4.8 % in Europeans; 6.2 % vs 4.7 % in Chinese; and 21.4 % vs 20.1 % in South Asians. There was much variation in individuals categorized by the ADA and WHO criteria. Agreement between the two for the diagnosis of previously unknown diabetes was only moderate (*kappa* statistics 0.42 to 0.59). Thus in the populations studied the new criteria would increase the prevalence of diabetes in addition to classifying some individuals diabetic by current criteria as non-diabetic. It should be stressed however that diagnosis of the individual should not be based on a single test.

***Diabet. Med.* 15: 554–557 (1998)**

KEY WORDS **diabetes; diagnostic criteria; American Diabetes Association; World Health Organization; impaired glucose tolerance; fasting plasma glucose; glucose tolerance test**

Received 3 February 1998; revised 27 February 1998; accepted 27 February 1998

Introduction

Recently the American Diabetes Association (ADA) adopted a new, lower, fasting blood glucose level (≥ 7.0 mmol l^{-1} for venous plasma) for the diagnosis of diabetes mellitus.[1] The new fasting level was based on analyses examining the cross-sectional relationship between fasting glucose concentrations and microvascular complications in three populations,[1–3] and on a consideration of a fasting level that gave a similar prevalence of diabetes to the 2 h OGTT level.[1,3,4] The ADA is, however, encouraging the use of fasting glucose as the main diagnostic test[1] rather than the oral glucose tolerance test (OGTT) as currently recommended by WHO.[5] Data presented in the expert committee report[1] demonstrated that the prevalence of diabetes in the Third National Health and Nutrition Examination Survey (NHANES III) was 14 % lower using the new criteria (i.e. the new fasting level without the 2 h post-challenge level). However, this may not be the case for all populations. The new ADA criteria also include the category 'impaired fasting glucose', abbreviated to IFG (6.1–6.9 mmol l^{-1} for venous plasma) which is described as being analogous to the category of impaired glucose tolerance (IGT), based on the 2 h OGTT result.

In this study we examine and compare the current WHO criteria with the new ADA criteria using data from a population-based study of three different ethnic groups in Newcastle upon Tyne.

Subjects, Methods, and Analysis

The methods of the study have been described in detail elsewhere.[6] Briefly all Chinese adults aged 25–64 years and rseident in Newcastle were eligible and were recruited through a name search of the Family Health

Sponsors: Department of Health; Northern and Yorkshire Regional Health Authority; Newcastle upon Tyne Health Authority; Barclay Trust; British Diabetic Association

* Correspondence to: Dr Nigel Unwin, Wellcome Research Laboratory, Royal Victoria Infirmary, Queen Victoria Road, Newcastle upon Tyne NE1 4LP, UK

 CCC 0742–3071/98/070554–04$17.50
© 1998 John Wiley & Sons, Ltd.

Services Authority (FHSA) patient register (the list of all people resident in Newcastle and registered with a general practitioner) and community contacts.[7] Three hundred and eighty men and women were seen, estimated to be 70 % of the target population. In addition, age and sex stratified random samples of European (used here to refer to people whose ancestral origins are from Europe) and South Asian (people whose ancestral origins are from the Indian sub-continent) adults aged 25–74 years were taken from the FHSA register. South Asian adults were sampled by identifying South Asian sounding names.[8] Overall 840 European and 708 South Asian adults were seen (response rates of 66 % and 63 %, respectively). All subjects who did not report having been given a diagnosis of diabetes by a doctor were asked to fast from 10 pm and underwent a standard WHO OGTT[5] between 8 am and 10 am the next morning. Fasting and 2 h plasma glucose were measured by the glucose oxidase method using an automated colorimetric method on a Hitachi 717 analyser. Diabetes and impaired glucose tolerance were based on 2 h post-glucose load venous plasma values following current WHO criteria (diabetes ≥ 11.1 mmol l^{-1}; impaired glucose tolerance 7.8–11.0 mmol l^{-1}). Using the new ADA criteria diabetes was defined as fasting venous plasma ≥ 7.0 mmol l^{-1}, and impaired fasting glucose as 6.1 to 6.9 mmol l^{-1}.

The age range of the Chinese population was less than that of the other two populations. We have chosen to examine the effect of the new ADA criteria on all the data available to us, rather than limiting the age range to 25–64 years for all the groups. To avoid confusion it is worth emphasizing that the aim of this study is not to compare the prevalence figures between the different ethnic groups but to examine the effect of the new ADA criteria within each group. All the prevalence figures have been age adjusted to the 1991 England and Wales population. This is so that others with similar data on other populations may age adjust to the same standard population for comparison to the figures presented here. Ninety-five per cent confidence intervals were calculated on the difference between the prevalence of diabetes as assessed by the two criteria. The *kappa* statistic[9] was used to assess the agreement between the two classifications for people previously unknown to have diabetes. This statistic measures the agreement between two classification systems beyond agreement that is expected by chance alone.

Results

Complete data were available on 824 European (25–74 years), 375 Chinese (25–64 years), and 680 South Asian (25–74 years) subjects. The prevalence of diabetes previously diagnosed by a physician was 2.3 %, 1.7 %, and 12.9 % in European, Chinese, and South Asian adults, respectively. The relationships between the new ADA and current WHO criteria are summarized in Table 1. People with known diabetes are included because the application of the new criteria will not change the status of those already carrying a diagnosis. Thus, Table 1 shows how the total prevalence of diabetes is affected in addition to the relationship between the prevalence of IGT and IFG. Based on the ADA criteria, using fasting plasma glucose only, the prevalence of diabetes was higher in all ethnic groups than based on current WHO criteria. The absolute difference in the European population was 2.3 % (95 % CI 1.3–3.3); in the Chinese population it was 1.5 % (0.3–2.7); and in the South Asian population it was 1.3 % (0.4–2.2). In both the European and Chinese populations the prevalence of the impaired fasting glucose category was higher using the ADA criteria than the current WHO category of impaired glucose tolerance. Again the difference was most marked in the European population (18.9 % vs 12.5 %). In the South Asian population the prevalence of impaired fasting glucose and impaired glucose tolerance was very similar (19.0 % vs 18.7 %). There were some marked changes in the classification of individuals between the current WHO and new fasting glucose ADA criteria. For example, 12.5 % of the European population had IGT, yet 5.9 % were normal and 1.8 % had diabetes on the ADA criteria; and of the 20.1 % of South Asians classified as having diabetes by WHO criteria 2.1 % were classified as not having diabetes on ADA criteria.

Table 2 shows the classification of people without a doctor diagnosis of diabetes by the current WHO criteria and the new ADA fasting criteria. Also shown in Table 2 are *kappa* statistics for the agreement between the two

Table 1. The relationship between normal, impaired and diabetic (known and new) categories using the new ADA fasting and WHO 2 h post glucose load criteria

WHO criteria (total %)	New ADA fasting criteria (total %)		
European ($n = 824$)	Normal (74.1)	IFG (18.9)	Diabetes (7.1)
Normal (82.7)	67.8	13.5	1.4
IGT (12.5)	5.9	4.9	1.8
Diabetes (4.8)	0.4	0.5	3.9
Chinese ($n = 375$)	Normal (79.3)	IFG (14.5)	Diabetes (6.2)
Normal (83.3)	72.5	9.8	1.0
IGT (12.0)	6.8	3.8	1.4
Diabetes (4.7)	0	0.9	3.8
S. Asian ($n = 680$)	Normal (59.7)	IFG (19.0)	Diabetes (21.4)
Normal (61.2)	49.8	10.2	1.2
IGT (18.7)	9.4	7.1	2.2
Diabetes (20.1)	0.5	1.6	17.9

All figures are percentages and age adjusted to the England and Wales population. People with a doctor diagnosis of diabetes are included in the diabetic category under both the ADA and WHO criteria. WHO criteria are those for epidemiological studies. Total prevalence figures (%) are shown in parentheses.
IGT, impaired glucose tolerance; IFG, impaired fasting glucose.

© 1998 John Wiley & Sons, Ltd.

Table 2. The relationship between newly diagnosed diabetes (i.e. no previous diagnosis reported) using the new ADA fasting and WHO 2 h post-glucose load criteria

WHO criteria	New ADA fasting criteria		
European ($n = 802$)	Normal or IFG	Diabetes	*kappa* (95% CIs)
Normal or IGT	740	33	0.42
Diabetes	11	18	(0.28–0.56)
Chinese ($n = 369$)	Normal or IFG	Diabetes	*kappa* (95% CIs)
Normal or IGT	350	8	0.58
Diabetes	3	8	(0.36–0.80)
S. Asian ($n = 576$)	Normal or IFG	Diabetes	*kappa* (95% CIs)
Normal or IGT	491	29	0.59
Diabetes	16	40	(0.48–0.70)

The figures are the number of individuals in each group.
IGT, impaired glucose tolerance; IFG, impaired fasting glucose.

classifications. *Kappa* values ranged from 0.42 (in the Europeans) to 0.59 (in the South Asians).

Discussion

Using fasting glucose as the main diagnostic test for diabetes offers several practical advantages. It is more convenient, less expensive, and more reliable (reproducible) than an oral glucose tolerance test.[1] The new fasting level has been chosen on cross-sectional evidence of its relationship with microvascular complications and on a consideration of what would give a similar prevalence in population studies to the WHO recommended 2 OGTT level. Thus the case for its use appears strong. However the analyses presented here suggests it would be prudent to treat this recommendation with some caution. First, the effect on the prevalence of diabetes in population-based studies may vary between populations. Data presented from NHANES III in the expert committee report[1] suggested the new fasting criteria result in a lower prevalence of diabetes, whereas the data we present here suggest the opposite. The reasons for this difference are not clear but it is worth noting that none of the 95 % confidence intervals presented here on the difference in prevalence between the two classifications included zero and indicates that the higher prevalences on new ADA criteria are unlikely to be due to chance. Secondly, there is much change in the classification of individuals between the WHO and new ADA criteria. In other words a person diagnosed as diabetic by one set may not be diabetic on the other, indeed they may even be classified as having 'normal glycaemia' on the other. Table 2 shows, for example, that of 29 European individuals classified as 'diabetic' on the 2 h OGTT WHO criteria 11 were classified as non-diabetic on the new fasting ADA criteria, and of the 51 classified as diabetic by the ADA criteria 33 were not diabetic on WHO criteria. The *kappa* values indicate that at best the agreement can be described as moderate[9]—a *kappa* value of 1 indicates perfect agreement. There could also be differences both in phenotype and in prognostic significance between the categories. The numbers of people with diabetes on either set of criteria in this study are relatively small and provide insufficient power to adequately investigate phenotypic differences.

It is worth stressing that for the diagnosis of diabetes it is uncertain which set of criteria are most appropriate for the individual. Both WHO and ADA stress that the diagnosis of the asymptomatic individual requires confirmation (i.e. a repeat test result in the diagnostic range) and we have no information on this. We can thus comment only on the use of the two sets of criteria for epidemiological purposes. Finally it is worth noting the very marked differences in the classification of individuals between impaired fasting glucose tolerance (as shown in Table 1). Although IFG is described as 'analogous' to IGT,[1] in our study populations it is very far from equivalent in terms of the individuals categorized. The prognostic significance of IGT is reasonably well characterized[10] and similar information is needed on IFG in order to help determine the utility of this diagnostic category.

In conclusion, the use of the new ADA fasting level for clinical diagnosis and prevalence surveys is a well reasoned pragmatic alternative to the OGTT. However, further information is required on the effect of the new ADA fasting criteria on the prevalence of diabetes in a wider variety of populations, and particularly on their long-term prognostic significance. If a single test is to be done we would still favour the 2 h test, but one should not underestimate the logistical and economic difficulties of performing OGTTs on a large scale. It is not unreasonable to use fasting glucose as a survey measure in order to provide an estimate of the prevalence of diabetes, providing that it is clearly stated and accepting that this will lose the opportunity to measure the prevalence of IGT.

Acknowledgements

For the Chinese study we thank J. Yuen, H.S. Chin, S.L. Cheung, F. Liu, A. Tang, E. Tang, P. Chen, S.F. Cole, the North East Chinese Association, the Wah Sen Sah, members of the Community Relations Council, and all members of the Chinese community who supported the project. For the South Asian study we thank N. Ahmad, D. Kaur, A. Kulkarni, A. Qureshi, J. Yallop, and the 20 interviewers who worked for the study, and also S. Mughal for much help and advice. M. Brown, M. Miller, C. Turner, A. McEwan, S. Patel, and H. Armstrong all helped to run the screening sessions; they were assisted at times by A. Motala, K. Ramaiya, and D. Singh. L. Walker is thanked for help with data preparation. The Department of Health, Northern and Yorkshire Regional

© 1998 John Wiley & Sons, Ltd.

Health Authority, Newcastle upon Tyne Health Authority, the Barclay Trust and the British Diabetic Association are thanked for financial support.

References

1. The Expert Committee on the Diagnosis and Classification of Diabetes Mellitus. Report of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus. *Diabetes Care* 1997; **20**: 1183–1197.
2. Engelgau M, Thompson T, Herman W, Boyle J, Aubert R, Kenny S *et al*. Comparison of fasting and 2-hour glucose and HBA1c levels for diagnosing diabetes: diagnostic criteria and performance revisited. *Diabetes Care* 1997; **20**: 785–791.
3. McCance DR, Hanson RL, Charles M-A, Jacobsson LTH, Pettitt DJ, Bennett PH *et al*. Comparison of tests for glycated haemoglobin and fasting and two hour plasma glucose concentrations as diagnostic methods for diabetes. *Br Med J* 1994; **308**: 1323–1328.
4. Finch C, Zimmet P, Alberti KGMM. Determining diabetes prevalence: a rational basis for the use of fasting plasma glucose concentrations. *Diabetic Med* 1990; **7**: 603–610.
5. World Health Organization. Diabetes Mellitus: Report of a Study Group. Technical Report Series No. 727. Geneva: WHO, 1985.
6. Unwin N, Harland J, White M, Bhopal R, Winocour P, Watson W *et al*. Body mass index, waist–hip ratio and glucose intolerance in Chinese and European adults. *J Epidemiol Comm Hlth* 1997; **51**: 160–166.
7. Harland J, White M, Bhopal R, Raybould S, Unwin N, Alberti KGMM. Identifying Chinese populations in the UK for epidemiological research: experience of a name analysis of the FHSA register. *Public Health* 1997; **111**: 331–337.
8. Coldman AJ, Braun T, Gallagher RP. The classification of ethnic status using name information. *J Epidemiol Comm Hlth* 1988; **42**: 390–395.
9. Altman D. *Practical Statistics for Medical Research*. London: Chapman & Hall, 1991: 404–408.
10. Holman R, ed. Expert workshop on impaired glucose tolerance. *Diabetic Med* 1996; **13**: S1–S32.

© 1998 John Wiley & Sons, Ltd.